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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,550	06/28/2001	Albert Collinson	BBC-083 A US	6240

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KENNETH P. ZWICKER
ABBOTT BIORESEARCH CENTER
100 RESEARCH DRIVE
WORCESTER, MA 01605

EXAMINER	
LEE, BETTY L	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 02/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/894,550	COLLINSON ET AL.	
	Examiner	Art Unit	
	Betty Lee, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-8,11-88 and 96-104* is/are pending in the application.

4a) Of the above claim(s) *5-8,11 and 32-88* is/are withdrawn from consideration.

5)☒ Claim(s) *4, 12-31* is/are allowed.

6)☒ Claim(s) *96-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed November 9, 2005 is acknowledged. The cancellation of claims 1-3 and 89-95 by the Applicant is noted. Claims 5-8,11 and 32-88 are withdrawn from consideration. Claims 4, 12-31 and newly added claims 96-104 are under examination. The text of those sections of Title 35 U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections Withdrawn
Claim Rejections - 35 USC § 103

The rejection of claims 12-31 under 35 U.S.C. 103(a) is withdrawn pursuant to Applicant's arguments of 11/9/2005 which were persuasive.

Claim Rejections - 35 USC § 112

The rejection of claims 12-31 under 35 U.S.C. 112, first paragraph as lacking enablement commensurate with the scope of the claims, is withdrawn pursuant to Applicant's arguments of 11/9/2005 which were persuasive.

New Claim Rejections Necessitated by Admendments

Claim Rejections - 35 USC § 103

The text of those sections of Title 35 U.S. Code, not included in this action can be found in a prior office action.

Claims 96-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luger, *et al* (of record) in view of Schmidt, *et al* (EP0218531) and Berg (US Patent 5622701).

The claimed invention is drawn to a dual specificity antibody, or antigen-binding portion thereof, that specifically binds interleukin-1α and interleukin-1β, wherein said dual-specificity antibody, or antigen-binding portion is capable of binding an antigen comprising the amino acid sequence of SEQ ID NO. 3. The claimed invention is further drawn to the dual specificity antibody, or antigen-binding portion thereof, that is fully human; chimeric; CDR grafted; humanized; comprising mouse variable region and human constant region amino sequences; comprising human heavy and light chain variable sequences containing one or more mouse CDRs; or comprising mouse heavy and light chain variable sequences containing one or more human CDRs capable of binding SEQ ID NO. 3.

Luger, *et al* teach a dual specific antibody to IL-1α and IL-1β which recognizes a common epitope on the interleukin molecules and which may be used to develop more sensitive immunoassays for the detection of IL-1 activity in body fluids during the pathogenesis of inflammatory diseases. Luger, *et al* do not teach that the antibodies are capable of specifically binding an antigen having the amino acid sequence of SEQ ID NO. 3 and do not teach humanizing the antibodies.

Schmidt, *et al* teach production of antibodies against immunogenic peptides of human IL-1 (pg 2, lines 30-45). Because the immunogenic peptides disclosed by Schmidt, *et al* comprise 10 consecutive amino acids of and thus share a common epitope with the antigen of instant SEQ ID NO: 3, the antibodies disclosed by Schmidt would be capable of binding the antigen of instant SEQ ID NO: 3 (A_Geneseq_21 Database, Jan 6, 2006, Result 4, AC No. AAP71394).

Berg teaches dual specificity antibodies, which are humanized or human antibodies. Berg teaches that the humanized light chain can comprise CDRs having amino acids sequences from the light chain of a mouse antibody, and having a variable region framework sequence substantially identical to a human light chain variable region framework sequence. Berg teaches that humanized heavy chain can comprise three CDRs having amino acid sequences from the corresponding mouse antibody heavy chain with a variable region framework identical to a human heavy chain variable region framework sequence (col 3, lines 36-51). In addition, Berg teaches humanized immunoglobulins have variable region framework residues from a human immunoglobulin and CDR from a mouse immunoglobulin (col 4, lines 37-42). Berg teaches that humanized imunoglobulins have variable region framework and CDRs from a mouse immunoglobulin (col 10, lines 37-41) and that the heavy and light chain variable region framework residues can be derived from the same or different human antibody sequences (col 10, lines 49-54). Berg also teaches that human antibodies can be produced from non-human transgenic mammals having transgenes encoding at least a seqment of the human Ig locus (col 12, lines 6-9). In addition, Berg teaches that bispecific (dual specific) or bifunctional antibodies have one binding site that binds to one moiety and a second binding site that specifically binds to a second moiety, which results in the ability to bind at least two different epitopes simultaneously (col 13, lines 9-20).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have made a dual specificity antibody with enhanced

sensitivity against both interleukin-1α and interleukin-1β, as taught by Lugar, and to have used the immunogenic peptides taught by Schmidt to be suitable for raising antibodies against interleukin-1. One of ordinary skill in the art at the time the invention was made would have found it *prima facie* obvious to have added the modifications of Berg in order to humanize the antibody and make it more useful for *in vivo* applications. The person of ordinary skill in the art at the time the invention was made would have been motivated to do so because an antibody with dual specificity to IL-1α and IL-1β would be able to neutralize IL-1 mediated inflammation more completely than an antibody directed against either alone.

Conclusion

Claims 4 and 12-31 are allowed. Claims 96-104 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Betty Lee, Ph.D. whose telephone number is (571) 272-8152. The examiner can normally be reached on M-F 9 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BLL

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600